

AMENDMENTS TO THE CLAIMS

Please cancel claims 1-11 without prejudice.

Please add claims 12-30.

The following is a complete listing of the claims:

Claims 1-11 (canceled without prejudice).

Claim 12 (new). A stable pharmaceutical dosage formulation for oral administration comprising a plurality of enteric coated pellets wherein each pellet consists essentially of :

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- a) a core consisting essentially of 10-50 weight percent based on the total weight of the core of omeprazole or a pharmaceutically acceptable salt thereof, a surface active agent, a filler, a binder and 0.5 to 10 weight percent based on the total weight of the core of a pharmaceutically acceptable alkaline agent, wherein the alkaline agent is selected from the group consisting of lysine and arginine; and
 - b) a coating layer surrounding the core that consists essentially of an enteric coating agent, 5 to 50 weight percent based on the total weight of the coating layer of an inert processing aid and optionally a plasticizer wherein the enteric coating layer is applied directly to the omeprazole containing core without a separating layer between the omeprazole containing core and enteric coating layer.

Claim 13 (new). The pharmaceutical dosage formulation as recited in claim 12 wherein the core consists essentially of 10 to 50 weight percent based on the total weight of the core of omeprazole, a surface active agent, a filler, a binder and 0.5 to 10 weight

percent based on the total weight of the core of a pharmaceutically acceptable alkaline agent, wherein the alkaline agent is selected from the group consisting of lysine and arginine.

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Claim 14 (new). The pharmaceutical dosage formulation as recited in claim 12 wherein the core consists essentially of 10 to 50 weight percent based on the total weight of the core of a pharmaceutically acceptable salt of omeprazole, a surface active agent, a filler, a binder and 0.5 to 10 weight percent based on the total weight of the core of a pharmaceutically acceptable alkaline agent, wherein the alkaline agent is selected from the group consisting of lysine and arginine.


Claim 15 (new). The pharmaceutical dosage formulation as recited in claim 12 wherein the plasticizer in the in the enteric coating is not optional.

Claim 16 (new). The pharmaceutical dosage formulation as recited in claim 12 wherein the enteric coating agent is selected from the group consisting of cellulose acetate phthalate, hydroxypropyl methyl cellulose phthalate, polyvinyl acetate phthalate, carboxymethylethyl cellulose, co-polymerized methacrylic acid/methacrylic acid methyl esters.

Claim 17 (new). The pharmaceutical dosage formulation as recited in claim 12 wherein the inert processing aid is selected from the group consisting of talc, silicon dioxide and magnesium stearate.

Claim 18 (new). The pharmaceutical dosage formulation as recited in claim 12 wherein the core consists essentially of 10 to 50 weight percent based on the total weight of the core of omeprazole, 0.20 to 2.0 weight percent based upon the total weight of the core


of a surface active agent, 20 to 90 weight percent based on the total weight of the core of a filler, 0.1 to 10 weight percent based on the total weight of the core of a binder and 1 to 3 weight percent based on the total weight of the core of a pharmaceutically acceptable alkaline agent, wherein the alkaline agent is selected from the group consisting of lysine and arginine.

 Claim 19 (new). The pharmaceutical dosage formulation as recited in claim 12 wherein the core consists essentially of 10 to 50 weight percent based on the total weight of the core of a pharmaceutically acceptable salt of omeprazole, 0.20 to 2.0 weight percent based upon the total weight of the core of a surface active agent, 20 to 90 weight percent based on the total weight of the core of a filler, 0.1 to 10 weight percent based on the total weight of the core of a binder and 1 to 3 weight percent based on the total weight of the core of a pharmaceutically acceptable alkaline agent, wherein the alkaline agent is selected from the group consisting of lysine and arginine.

Claim 20 (new). A stable pharmaceutical dosage formulation for oral administration comprising a plurality of enteric coated pellets wherein each pellet consists of essentially of :

(a) a core consisting essentially of: (a) an inert core and (b) a drug layer consisting essentially of 10-50 weight percent based on the total weight of the core of omeprazole or a pharmaceutically acceptable salt, a surface active agent, a filler, a binder and 0.5 to 10 weight percent based on the total weight of the core of a pharmaceutically acceptable alkaline agent, wherein the alkaline agent is selected from the group consisting of lysine and arginine; and

(b) a coating layer surrounding the core that consists essentially of an enteric coating agent, 5 to 50 weight percent based on the total weight of the coating layer of an inert processing aid and optionally a plasticizer wherein the enteric coating layer is applied directly to the omeprazole containing core without a separating layer between the omeprazole containing core and enteric coating layer.

 Claim 21 (new). The pharmaceutical dosage formulation as recited in claim 20 wherein the drug layer consists essentially of 10 to 50 weight percent based on the total weight of the core of omeprazole, a surface active agent, a filler, a binder and 0.5 to 10 weight percent based on the total weight of the core of a pharmaceutically acceptable alkaline agent, wherein the alkaline agent is selected from the group consisting of lysine and arginine.

Claim 22 (new). The pharmaceutical dosage formulation as recited in claim 20 wherein the drug layer consists essentially of 10 to 50 weight percent based on the total weight of the core of a pharmaceutically acceptable salt of omeprazole, a surface active agent, a filler, a binder and 0.5 to 10 weight percent based on the total weight of the core of a pharmaceutically acceptable alkaline agent, wherein the alkaline agent is selected from the group consisting of lysine and arginine.

Claim 23 (new). The pharmaceutical dosage formulation as recited in claim 20 wherein the plasticizer in the in the enteric coating is not optional.

Claim 24 (new). The pharmaceutical dosage formulation as recited in claim 20 wherein the enteric coating agent is selected from the group consisting of cellulose acetate phthalate, hydroxypropyl methyl cellulose phthalate, polyvinyl acetate phthalate,

carboxymethylethyl cellulose, co-polymerized methacrylic acid/methacrylic acid methyl esters.

Claim 25 (new). The pharmaceutical dosage formulation as recited in claim 20 wherein the inert processing aid is selected from the group consisting of talc, silicon dioxide and magnesium stearate.

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Claim 26 (new). The pharmaceutical dosage formulation as recited in claim 20 wherein the drug layer consists essentially of 10 to 50 weight percent based on the total weight of the core of omeprazole, 0.20 to 2.0 weight percent based upon the total weight of the core of a surface active agent, 20 to 90 weight percent based on the total weight of the core of a filler, 0.1 to 10 weight percent based on the total weight of the core of a binder and 1 to 3 weight percent based on the total weight of the core of a pharmaceutically acceptable alkaline agent, wherein the alkaline agent is selected from the group consisting of lysine and arginine.

Claim 27 (new). The pharmaceutical dosage formulation as recited in claim 20 wherein the drug layer consists essentially of 10 to 50 weight percent based on the total weight of the core of a pharmaceutically acceptable salt of omeprazole, 0.20 to 2.0 weight percent based upon the total weight of the core of a surface active agent, 20 to 90 weight percent based on the total weight of the core of a filler, 0.1 to 10 weight percent based on the total weight of the core of a binder and 1 to 3 weight percent based on the total weight of the core of a pharmaceutically acceptable alkaline agent, wherein the alkaline agent is selected from the group consisting of lysine and arginine.

Claim 28 (new). A method for preparing a stable oral pharmaceutical dosage

formulation which consists essentially of:

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- (a) forming a pellet core consisting essentially of 10 to 50 weight percent based on the total weight of the core of omeprazole or a pharmaceutically acceptable salt, a surface active agent, a filler, a binder and 0.5 to 10 weight percent based on the total weight of the core of a pharmaceutically acceptable alkaline agent, wherein the alkaline agent is selected from the group consisting of lysine and arginine; and
 - (b) applying an enteric coating directly onto the core without a separating layer wherein the enteric coating layer surrounds the core and consists essentially of an enteric coating agent, 5 to 50 weight percent based on the total weight of the coating layer of an inert processing aid and optionally a plasticizer.

Claim 29 (new). The method recited in claim 28 wherein the enteric coating layer is applied from an organic solvent based system.

Claim 30 (new). The method recited in claim 28 wherein the step of forming the core further comprises the step of applying the core ingredients onto an inert core.
